Venous leg ulcers: patient concordance with compression therapy and its impact on healing and prevention of recurrence

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ABSTRACT

This study aimed to review available data on the reasons attributed to patient non concordance with compression therapy for the treatment of venous leg ulcers (VLUs), the frequency of non concordance and its effects on clinical outcomes. The biomedical literature was searched for publications on VLUs, compression therapy and concordance over the past 20 years. Physical, aesthetic and cosmetic factors, patient lack of education about VLUs, cost of therapy and issues with treatment by clinicians were all reported to influence concordance with compression therapy. The search identified 10 studies reporting patient concordance with compression stockings or bandages; while non concordance ranged from 2% to 42% of patients in three randomised controlled trials, it was generally higher in real-world studies, ranging from 9.7% to 80%. Another set of six studies indicated that the healing rate was half and the median time to complete healing was twice as long when patients were not concordant. Further, recurrence rates were 2–20 times greater when patients did not comply with the use of stockings following VLU healing. In conclusion, published biomedical literature has documented that non concordance with compression therapy negatively impacts the outcome of VLUs, highlighting the need to improve patient concordance to maximise therapeutic benefits.

Key words: Compression therapy • Concordance • Healing • Recurrence • Venous leg ulcers

Key Points

- compression therapy is the mainstay of treatment for venous leg ulcers (VLUs) and it is generally accepted that poor concordance with compression therapy ultimately affects ulcer healing and recurrence
- six factors were reported to influence concordance: physical factors, patients' lack of education about their condition and the treatment prescribed, aesthetic and cosmetic factors, clinician issues, and less commonly, the cost of therapy
- compression therapy is the mainstay of treatment for venous leg ulcers (VLUs) and it is generally accepted that poor concordance with compression therapy ultimately affects ulcer healing and recurrence

INTRODUCTION

Venous leg ulcers (VLUs), resulting from venous insufficiency that ultimately causes the development of tissue trauma (1), represent the vast majority (80% to 85%) of all leg ulcers, the balance of which includes ulcers of arterial or mixed aetiology (2).

Although a number of well established or emerging treatments are available, compression therapy, otherwise shown to be detrimental to people with arterial disease (3,4), is considered the mainstay of treatment and prevention of recurrence for leg ulcers of venous origin (5). Systems available for compression therapy include: compression bandages, largely used for VLU treatment (4,6); elastic hosiery which is considered the mainstay for prevention of VLU recurrence (4); and, more rarely reported, intermittent pneumatic

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compression (IPC) (4,6) which can be used on its own, but is usually combined with the use of compression bandages for VLU healing. The attributes of compression therapy in VLU healing include improvement of venous return, reduction of oedema of the lower extremities, physical protection of wounds from bacterial infections, elevation of wound temperatures and thrombolysis (4).

Numerous studies have evaluated the effectiveness of different compression therapy systems on VLU healing and on recurrence after healing by measuring the rates of healing or recurrence. Although the outcome measures in these trials vary considerably, making it difficult to compare the effectiveness of one system with another, results of Cochrane systematic reviews show that ulcer healing increases with the use of compression hosiery or bandages (7), and may also increase with the use of IPC when compared with no compression (8). In addition, from a separate systematic review, it was reported that although no trials compared rates of recurrence with and without compression therapy, some studies report that not wearing compression is associated with VLU recurrence and therefore provide indirect evidence that the use of compression therapy reduces ulcer recurrence (9).

There is evidence that the profile of leg ulcer patients may be changing as a result of the increasing age of VLU patients; different aetiological factors and concurrent medical or psychosocial issues may have an impact on leg ulceration (10,11). Factors reported to influence either VLU healing, recurrence or both include lifestyle habits (poor mobility (12), poor diet and smoking (13)), underlying medical conditions (popliteal vein insufficiency (14), history of deep venous thrombosis or deep venous insufficiency (12,15)), and the characteristics of the compression device such as the unsuitability of compression stockings for some patients (12), or the variability of the pressure provided (16). In addition, VLU characteristics, such as having a VLU for more than 4 months (12,15), large initial ulcer size, previous ulcer size greater than 10 cm^2 ((14,15,17) or if the VLU is a recurrent lesion (15), all affect either healing or recurrence or both. Apart from these, one issue commonly raised with the use of compression therapy for VLU healing and prevention of recurrence is patient non concordance with their prescribed treatment (18,19).

The aim of this study was to review available data on the reasons attributed to non concordance, the frequency of non concordance and the effects of non concordance on clinical outcomes of VLUs.

METHODS

A literature search was performed to obtain any original studies pertaining to the phenomenon of non concordance, the frequency of concordance with compression therapy among VLU patients and the effects of non concordance on VLU healing and recurrence. Relevant studies published over the 20-year period prior to July 2008 were identified from PubMed and Cochrane databases using the following search algorithm: VLU AND compression therapy AND (compliance OR concordance OR adherence). English language articles were primarily reviewed, along with promising articles in other languages. Bibliographies of retrieved articles were screened to identify additional sources of information and recent review articles were used as available. Articles spanning 1988 to 2008 were retrieved. Only real-world studies or randomised controlled trials that focused on compression therapy for treating or preventing leg ulcers of venous aetiology were taken into consideration. In all the studies included, concordance was primarily reported by the patients themselves except one where concordance was assessed by the health care professionals. The published criteria for concordance were used for each study as reported and are described in the Results section.

Throughout this article, the term concordance, used to describe the consistency with which a patient follows the prescribed therapy for treating VLU or preventing VLU recurrence, also refers to compliance and adherence. In addition, the term non concordance encompasses both non and poor concordance.

RESULTS

Determinants of non concordance

A number of different factors were reported in the literature as potential determinants of VLU patient non concordance with compression therapy (Table 1). Some patients do not have a clear understanding of their condition or the therapy they have been prescribed (20,21); as a consequence, wearing stockings may seem

Key Points

- non concordance with the use of compression stockings or bandages ranged from 2% to 80% of patients, with values from 2% to 42% reported from three randomised controlled trials and values from 9.7% to 80% from real-world studies
- non concordance leads to decreased healing rates and increased recurrence rates and thereby reduces the effectiveness of compression therapy
- VLU healing rate was half and the median time to complete healing was twice as long when concordance with compression therapy was poor
- the recurrence rates of VLUs were 2–20 times greater when patients did not comply with the use of stockings following healing of VLUs
- the use of compression therapy is reported to be effective; however, there are many unmet needs with current treatment options
- despite the lack of direct evidence in the literature, indirect association suggests that patient concordance with compression therapy has a negative impact on both quality of life (QoL) and economic outcomes of VLU treatment
- the ideal compression system would enhance concordance to treatment by being simple to use and comfortable to wear, enable patients to apply and remove it themselves, allowing them to bathe and wash. The burden of treatment for the patient would be reduced, providing more freedom, and allow the patient to be more in control and involved in their own care
- poor or non concordance with compression therapy has a negative impact on the outcome of VLUs, highlighting the need to increase concordance with compression therapy to maximise therapeutic benefits

Key Points

- six factors were reported to influence concordance: physical factors, patients' lack of education about their condition and the treatment rescribed,aesthetic and cosmetic factors, clinician issues, and less commonly, the cost of therapy

Table 1 Determinants of non concordance

Patients' lack of education about VLUs	Patients do not have a clear understanding of their condition or of the treatment prescribed (20,21,28)
	Patients think wearing stockings is unnecessary (22)
	Incorrect application (16,29)
Physical factors	Pain (20,21)
	Leakage of exudate (21)
	Skin irritation (20,21)
	Discomfort (22,23)
	Difficulty in putting on the stockings (20,23)
Aesthetic and cosmetic factors	Very unaesthetic devices (20,23)
	Restricted choice of footwear and clothing (20,21)
	Restricted ability to bathe or shower (13)
Psychological factors	Poor relationship with health care team (25)
	Poor social relationships (25)
	Additional life stresses (25)
Economic factors	Cost of therapy (23,27)
Clinician issues	Poor assessment of patient VLU (5)
	Inappropriate choice of garment (24)
	Incorrect application (5)
	Lack of knowledge about wound care (18)

unnecessary (22). Physical factors including pain (20,21), leakage of exudate (21), skin irritation (20,21), discomfort (22,23) and difficulty in putting on the stockings (20,23) also negatively influence patient concordance with compression therapy. Clinician issues such as poor wound assessment, inappropriate choice of garment or incorrect application of the compression device that may render the therapy painful, or lack of knowledge about wound care have also been implicated (5,18,24). Aesthetic and cosmetic issues include the perceived unattractiveness of the devices (20,23), the limitations on choice of clothing and footwear (20,21) and restriction of the ability to bathe or shower (13). Psychological factors, including the quality of the relationship between a patient and their health care team, the quality of the patient's social relationships or potential additional life stresses were also reported to impact concordance with therapy (25,26). Economic factors, including cost of therapy (23,27), were also mentioned.

Frequency of non concordance with compression therapy

The literature search identified 10 studies (12,20,22,27,30–35), either controlled clinical trials (where, by study design, patient behaviour is more closely overseen) or real-world studies, that reported the frequency of patient concordance with compression therapy for the treatment of VLUs (Figure 1). In these studies, concordance is generally defined as the extent to which the prescribed compression system is worn or the prescribed

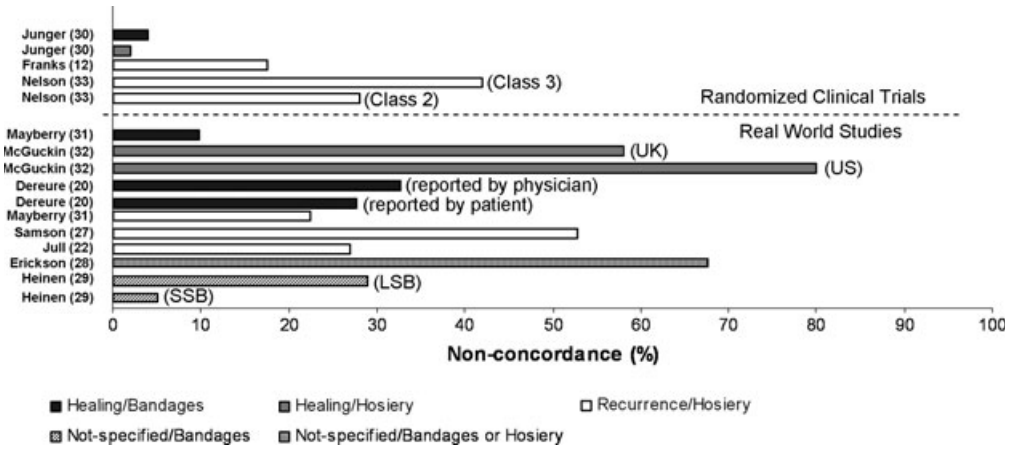

Figure 1. Proportions of VLU patients non concordant with compression therapy. The percentage of patients non concordant with their prescribed compression therapy for VLU healing (filled bars) or prevention of recurrence (clear bars), or healing or recurrence not specified (hatched bars) are shown. Nelson (Class 3): patients treated with higher pressure stockings; Nelson (Class 2): patients treated with lower pressure stockings; Dereure: concordance was reported both by the physician and the patient; Heinen (LSB): patients treated with stockings or long-stretch bandages; Heinen (SSB): patients treated with short-stretch bandages.

treatment regimen followed, although one study also included patient attendance at scheduled appointments and success or failure in following instructions regarding wound and extremity care as components of patient concordance (30). Regarding reporting of concordance, this was primarily detailed by the patient either at follow-up visits or using a diary (12,22,27,31–34); in one study, concordance was also assessed by the physician with similar results (20). In another one, concordance was evaluated during the treatment period by the vascular nurse clinician based on patient attendance at scheduled appointments and capability to follow the prescribed regimen. Overall, studies reported percentages of concordance for either healing or recurrence that ranged widely, from 2% to 80% of patients (32,34) with values from 2% to 42% reported from three randomised controlled trials and values from 9.7% to 80% from real-world studies. When only ulcer healing was considered, rates of non concordance were the lowest, ranging from 2% to 4%, in a randomised controlled trial (32) whereas rates of non concordance ranged from 10% to 80% in three real-world studies (20,33,34) (Figure 1). Among patients treated exclusively with compression hosiery for the prevention of VLU recurrence, 17.5% to 42% were poorly concordant or non concordant in two randomised controlled trials (12,35) and 22% to 53% in three real-world studies (22,27,33). In two real-world studies (30,31) where no discrimination was made between healing and prevention of recurrence for reporting concordance, 5% to 68% non concordance with compression bandages or hosiery treatment were reported.

Non concordance influences the effectiveness of compression therapy

Although VLU healing and prevention of recurrence are often suggested as being hindered by non concordance with compression therapy, actual data available on this topic are scarce. A total of six studies from Europe and the USA were published between 1988 and 2004 that differentially reported clinical outcomes of using compression therapy, limited to compression hosiery and bandages, for concordant versus non concordant patients (14,24,27,30,33,36). Three of these studies investigated healing rates, one of which evaluated healing after ulcer excision and skin grafting (14,30,33); five of the six studies reported VLU recurrence rates or time to recurrence in concordant versus non concordant patients (24,27,30,33,36).

Three real-world studies considered VLU healing according to patient concordance with compression hosiery only or with a non specified compression system (14,30,33). Over a follow-up period of 2–40 months, the healing rate was half and the median time to complete healing was twice as long when concordance with compression therapy was poor (Table 2). Mayberry and colleagues considered a population of 102 VLU patients and observed a healing rate of 97% at 40 months in the concordant group versus 55% in the non concordant group (33). In a study of 99 patients by Erickson and colleagues, the time to healing decreased from 4.3 months in the non concordant to 2.4 months in the concordant group of patients (30). In their retrospective cohort study, using multivariate regression analysis, Kjaer and colleagues reported that, over a 12-month period, non concordance with compression therapy was inversely correlated with ulcer healing with an odds ratio for healing of 0.27 ($P = 0.01$) for non concordant patients (14).

According to five different studies, when compression hosiery is used for the prevention of VLU, poor concordance leads to increased recurrence rates and decreased time to recurrence (Table 2). In the three real-world studies (27,30,33) over a period of 24–60 months, recurrence rates were 1.7–20 times greater when patients did not comply with the use of stockings following healing of the VLUs. In the two randomised clinical trials (24,36) conducted over a 12-month period, recurrence rates were 2–9 times greater when patients were non concordant.

DISCUSSION

From a total of 10 studies retrieved that considered patient concordance with compression therapy for VLU treatment or for the prevention of VLU recurrence, non concordance was reported to range from 2% to 80%. This wide range can at least partly be explained by concordance with treatment often being higher in the context of a clinical trial structure than in the real-world studies.

Many factors are reported in the biomedical literature to explain VLU patient non

Key Points

- non concordance with the use of compression stockings or bandages ranged from 2% to 80% of patients, with values from 2% to 42% reported from three randomised controlled trials and values from 9.7% to 80% from real-world studies
- non concordance leads to decreased healing rates and increased recurrence rates and thereby reduces the effectiveness of compression therapy
- the recurrence rates of VLUs were 2–20 times greater when patients did not comply with the use of stockings following healing of VLUs

Table 2 Non concordance and effectiveness of compression bandages or hosiery for VLU healing

Study, year, country	Type of study	Types of compression	Definition of non concordant patients	Outcome measures	Outcome for: Concordant group (number of patients)	Outcome for: Non concordant group (number of patients)
Mayberry et al., 1991, USA (33)	Real-world study	Hosiery	Those who consistently refused to use ambulatory elastic compression	Healing rate	97% at 40 months* (102)	55% at 40 months (11)
Erickson et al., 1995, USA (30)	Real-world study	Hosiery Bandages	Those who show less than 100% attendance at scheduled clinic appointments, less than 100% concordance with compression therapy and who fail to follow all instructions regarding wound and extremity care	Time to healing	2.4 months	4.3 months
				Healing rate	73% at 5 months 97% at 24 months (32)	59% at 5 months 89.6% at 24 months (67)
Kjaer et al., 2003, Denmark (14)	Real-world study	Hosiery Bandages	Those who exhibit presence of oedema caused by insufficient compression at postoperative visits	Ulcer healing after grafting		OR = 0.27 (95% CI: 0.09–0.51) at 12 months (113)
Blair et al., 1988, UK (36)	Randomised clinical trial	Hosiery (high pressure)	Those who did not wear stockings regularly at 12 months	Rate of recurrence	22% at 12 months (111)	45% at 12 months (15)
Mayberry et al., 1991, USA (33)	Real-world study	Hosiery	Those who consistently refused to use ambulatory elastic compression	Time to recurrence	61.7 months	15.5 months
				Rate of recurrence	29% at 24 months (102)	100% at 36 months (11)
Erickson et al., 1995, USA (30)	Real-world study	Hosiery Bandages	Those who show less than 100% attendance at scheduled clinic appointments, less than 100% concordance with compression therapy and who fail to follow all instructions regarding wound and extremity care	Rate of recurrence	41% at 24 months (32)	71% at 24 months (67)
Samson and Showalter, 1996, USA (27)	Real-world study	Hosiery	Those who wore loose or worn-out stockings or who wore stockings irregularly or not at all	Rate of recurrence	4% at 69 months (25)	79% at 69 months (28)
Brooks et al., 2004, UK (24)	Randomised clinical study	Hosiery	Those who are not in the group taken care of by nurses educated for enhancing patient concordance	Rate of recurrence	4% at 12 months (21)	36% at 12 months (30)

CI: confidence interval; OR: odds ratio.

*Follow-up periods have all been converted into months.

concordance with compression therapy, including patient-centred physical, psychological, educational, and economic measures and also health care professional parameters. Concordance, primarily reported by the patients themselves in the studies captured here, is a complex phenomenon that also involves the relationship with the clinician (37,28). Depending on who is evaluating concordance, the patient or the health care professional, this estimate may vary.

Although poor concordance with compression therapy is often implicated in decreased VLU healing rates, studies investigating the effectiveness of such therapies do not often consider this component. Six studies were retrieved that evaluated the effectiveness of compression therapy for the treatment of VLUs or the prevention of their recurrence; but because of variability in the outcome measures for both healing and recurrence, results are difficult to compare. According to these studies, patient concordance with compression therapy does influence the course of VLU healing and, once healed, the prevention of VLU recurrence. Non concordance leads to decreased healing rates and increased recurrence rates and thereby reduces the effectiveness of compression therapy. Overall, the healing rate is half and the median time to complete VLU healing is twice as long when concordance with compression therapy is poor. Following healing of VLUs, recurrence rates are reported to be 2–20 times greater when patients do not comply with the use of stockings in real-world studies and 2–9 times greater in randomised clinical trials.

The impact of concordance with compression therapy on VLU recurrence varies widely. This can be partly explained by the variable length of follow-up periods and the different parameters used to evaluate patient concordance. For example, in the randomised clinical trial conducted by Brooks and colleagues (24) with a short follow-up of 12 months, the recurrence rate was 9 times greater in the non concordant than in the concordant group of patients. Interestingly, in that study, a concordant patient was defined as a patient who was exposed to an education program on VLUs as opposed to the more common qualification as a patient who consistently wore the prescribed compression therapy. As another example, in their real-world study, where non concordant patients were defined as those who wore loose or worn-out stockings or who wore them irregularly or not at all, Samson and colleagues (27), over a longer period of 69 months, reported a 20 times greater recurrence rate in the non concordant than in the concordant group of patients. Overall, the longer the follow-up period, the larger the difference in recurrence rates between concordant and non concordant patients.

Compression therapy, used properly, is effective for treating VLUs; however, there are a variety of unmet needs with current treatment options. Inelastic bandages, for example, do not adapt to volume changes of the legs and require frequent reapplication; they provide high working pressure and low resting pressure, and pressure is maintained only over a short period of time (4,16). Elastic bandages are difficult to put on properly, and although they provide high pressure at the ankle that decreases towards the thigh, they can be dangerous for patients with arterial occlusive disease (3,4). Compression stockings are difficult to put on properly as well and often have to be custom-made to fit properly (4). Therefore the disadvantages of compression bandages include both the need for highly skilled clinicians to apply them and the variability of pressure achieved even when applied by skilled professionals (16,38). There are also restrictions that compression bandages may place on wearers which include, for example, limitations in activities of daily living such as showering (13) or reduction in ankle mobility (26).

Despite a lack of direct evidence in the literature, indirect association suggests that patient non concordance with compression therapy has a negative impact on both QoL and economic outcomes of VLU treatment. Specifically because patient QoL is significantly negatively affected by VLUs (39–41), and because healing rates decrease and recurrence rates increase with poor concordance with compression therapy, poor concordance is likely to reduce health-related QoL.

Costs associated with VLU treatment include direct costs such as those for drugs, dressings and bandages, costs related to care and hospital facilities, risk and complications (42) and indirect costs such as those as a result of loss of productivity and intangibles such as reduced QoL (43). Because VLU healing

Key Points

- VLU healing rate was half and the median time to complete healing was twice as long when concordance with compression therapy was poor
- the recurrence rates of VLUs were 2–20 times greater when patients did not comply with the use of stockings following healing of VLUs
- the use of compression therapy is reported to be effective; however, there are many unmet needs with current treatment options
- despite the lack of direct evidence in the literature, indirect association suggests that patient concordance with compression therapy has a negative impact on both quality of life (QoL) and economic outcomes of VLU treatment

Key Points

- the ideal compression system would enhance concordance to treatment by being simple to use and comfortable to wear, enable patients to apply and remove it themselves, allowing them to bathe and wash. The burden of treatment for the patient would be reduced, providing more freedom, and allow the patient to be more in control and involved in their own care
- poor or non concordance with compression therapy has a negative impact on the outcome of VLUs, highlighting the need to increase concordance with compression therapy to maximise therapeutic benefits

is delayed and recurrence increases when patients do not comply with compression therapy, poor concordance is extremely likely to increase the costs of treating VLUs.

Improving patient concordance with compression therapy for the treatment of VLUs should therefore be a goal to improve health-related QoL and to reduce the costs of treating VLUs. As suggested by Van Hecke and colleagues (19), concordance enhancing interventions should target three variables: (i) the type of compression therapy which ideally would allow increased ease of use, easier simple activities such as bathing and showering, increased social interactions and physical activity and better aesthetic features; (ii) the health care system through the setting up of peer or community support groups and (iii) patient education and motivation with comprehensive educational programs because patients involved in their treatment are more likely to be concordant (26).

Taken together, these data suggest that the ideal compression system would enhance concordance to treatment by being simple to use and comfortable to wear, enable patients to apply and remove it themselves, allowing them to bathe and wash. The burden of treatment for the patient would be reduced, providing more freedom, and allow the patient to be more in control and involved in their own care.

There are a number of limitations to this study. First, the studies included in this analysis used differing criteria to define concordance and non concordance, making it difficult to fairly compare one study with another. There is also a large variability in the type of compression therapy and material used from study to study. For instance, differences in knit, stiffness, and types of material used for stockings can influence comfort; stockings made on circular needles cause tourniquet effects compared with flat knit stockings; how these fundamental issues influence concordance is not known (44). In addition, the duration of patient follow-up varies widely from one study to another, likely influencing outcomes both in terms of healing and recurrence. Some differences in healing rates between concordant and non concordant patients seem striking (33) but other factors not taken into account may explain part of these differences. For example, patient characteristics and access to products were not taken into consideration when measuring a concordant behaviour. Finally, because concordance was primarily self-reported by the patient, value-laden judgements may be reflected.

Despite limitations inherent to the design of the studies reported, these data underline the extent of non concordance of VLU patients with compression therapy as well as its negative effects on treatment outcomes in terms of effectiveness of treatment, and indirectly, economic outcomes and health-related QoL. Innovative measures to increase concordance are needed to maximise therapeutic benefits.

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